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PTO/SB/21 (09-04)

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/695,578
	Filing Date	October 27, 2003
	First Named Inventor	Scott A. Waldman
	Art Unit	To Be Determined
	Examiner Name	To Be Determined
Total Number of Pages in This Submission	Attorney Docket Number	TJU0006-101 (WAL_SCO_005)

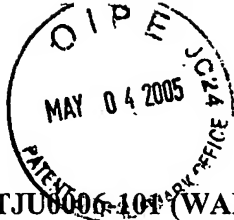
ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Citation Sheets (6 pp); (49) References Cited, (4) References Enclosed.
<b>Remarks</b> Express Mail Label No. EV 536020062 US Date of Deposit: May 4, 2005		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm	Cozen O'Connor		
Signature			
Printed Name	Mark DeLuca		
Date	May 4, 2005	Reg. No.	33,229

CERTIFICATE OF TRANSMISSION/MAILING			
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TJU0006-101 (WAL\_SCO\_005)

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of: **Scott A. Waldman**

Serial No.: **10/695,578**

Group Art Unit: **To Be Determined**

Filing Date: **October 27, 2003**

Examiner: **To Be Determined**

For: **Metastatic Colorectal Cancer Vaccine**

**EXPRESS MAIL INFORMATION**

Express Mail Label No: **EV 536020062 US**

Date Of Deposit: **May 4, 2005**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Forms SB/08a and SB/08b, including copies of PTO Forms 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

**This Information Disclosure Statement is being filed:**

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before** the mailing date of a first Office Action on the merits.
- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
  - ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);

or

- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ after the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), (see "Statement," and "Fees" below).
- ☒ Copies of the references BI, BO, BP and BT listed on the attached PTO Forms SB/08a and SB/08b, formerly known as PTO Form 1449 are enclosed.

**EXCEPT THAT:**

- ☐ In view of the voluminous nature of reference @@, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with 37 C.F.R. § 1.98(d), copies of the remaining references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) Serial No. 09/180,237 for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

**Statement under 37 C.F.R. § 1.97(e)**

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$\_\_\_\_\_. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☒ No fee or Statement is required under 37 C.F.R. § 1.97(b) as Applicant has not yet received an Office Action on the merits.

Respectfully submitted,



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Mark DeLuca  
Registration No. 33,229

Dated: May 4, 2005

COZEN O'CONNOR, P.C.  
1900 Market Street, 5<sup>th</sup> Floor  
Philadelphia, PA 19103-3508  
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(215) 701-2013 - Facsimile



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU0006-101	Serial No. 10/695,578
		Applicant  Scott A. Waldman et al.	
		Filing Date 10/27/2003	Group To Be Determined
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	AA	Almenoff et al., "Induction of heat-stable enterotoxin receptor activity by a human Alu repeat," <i>J. Biol. Chem.</i> , 1994, 269(24), 16610-16617	
	AB	Berd et al., "Immunization with Haptenized, Autologous Tumor Cells Induces Inflammation of Human Melanoma Metastases", <i>Cancer Res.</i> , 1991, 51, 2731-2734	
	AC	Berd et al., "Induction of Cell-mediated Immunity to Autologous Melanoma Cells and Regression of Metastases after Treatment with a Melanoma Cell Vaccine Preceded by Cyclophosphamide", <i>Cancer Res.</i> , 1986, 46, 2572-2577	
	AD	Carrithers et al., "Escherichia coli heat-stable toxin receptors in human colonic tumors," <i>Gastroenterology</i> , 1994, 107, 1653-1661	
	AE	Carrithers et al., "Escherichia coli heat-stable enterotoxin receptors. A novel marker for colorectal tumors," <i>Diseases Colon &amp; Rectum</i> , 1996, 39(2), 171-181	
	AF	Francis et al., Peptide Vaccines Based on Enhanced Immunogenicity of Peptide Epitopes Presented with T-Cell Determinants or Hepatitis B Core Protein", <i>Methods in Enzymol.</i> , 1989, 178, 659-676	
	AG	MacLean et al., "Immunization of breast cancer patients using a synthetic sialyl-Tn glycoconjugate plus Detox adjuvant", <i>Cancer Immunol. Immunother.</i> , 1993, 36, 215-222	
	AH	Miller et al., "The Induction of Hapten-Specific T Cell Tolerance by Using Hapten-Modified Lymphoid Cells", <i>J. Immunol.</i> , 1976, 117(5:1), 1519-1526	
	AI	Rudner et al., "Regulation of cell signaling by the cytoplasmic domains of the heat-stable enterotoxin receptor: Identification of autoinhibitory and activating motifs", <i>Proc. Natl. Acad. Sci.</i> , 1995, 92, 5169-5173	
	AJ	Sad et al., "Bypass of carrier-induced epitope-specific suppression using a T-helper epitope", <i>Immunology</i> , 1992, 76, 599-603	
	AK	Waldman et al., "Immunoaffinity Purification of Soluble Guanylyl Cyclase", <i>Methods Enzymol.</i> , 1991, 195, 391-396	
EXAMINER		DATE CONSIDERED	

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. TJU0006-101	Serial No. 10/695,578
	Applicant Scott A. Waldman et al.	
	Filing Date 10/27/2003	Group To Be Determined

## U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	AL	4,022,878	05/10/77	Gross	424	1.5
	AM	4,329,281	05/11/82	Christenson et al.	260	112 B
	AN	4,526,716	07/02/85	Stevens	260	112.5 R
	AO	4,736,866	04/12/88	Leder et al.	800	1
	AP	4,873,191	10/10/89	Wagner et al.	435	172.3
	AQ	4,945,050	07/31/90	Sanford et al.	435	172.1
	AR	5,017,487	05/21/91	Stunnenberg et al.	435	172.3
	AS	5,037,645	08/06/91	Strahilevitz	424	85.8
	AT	5,112,606	05/12/92	Shiosaka et al.	530	389.2
	AU	5,352,775	10/04/94	Albertsen et al.	536	23.1
	AV	5,518,888	05/21/96	Waldman	435	7.23
	AW	5,601,990	02/11/97	Waldman	435	7.23

## FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	AX	WO 90/11092	10/04/90	PCT	X	
	AY	WO 95/11694	05/04/95	PCT	X	
EXAMINER				DATE CONSIDERED		

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. TJU0006-101	Serial No. 10/695,578
	Applicant Scott A. Waldman et al.	
	Filing Date 10/27/2003	Group To Be Determined

## U. S. PATENT DOCUMENTS

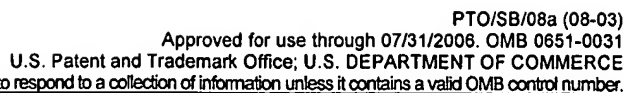
Examiner Initial		Document No.	Date	Name	Class	Subclass
	AA	5,518,888	5/21/96	Waldman et al.	435	7.23
	AB	5,601,990	2/11/97	Waldman et al.	435	7.23
	AC	5,731,159	3/24/98	Waldman et al.	435	7.23
	AD	5,879,656	3/9/99	Waldman et al.	424	149
	AE					
	AF					
	AG					
	AH					
	AI					
	AJ					

## FOREIGN PATENT DOCUMENTS

Examiner Initial					
	AK				
	AL				
	AM				
	AN				
	AO				

EXAMINER

DATE CONSIDERED



Substitute for form 1449A-PTD

*(Use as many sheets as necessary)*

Sheet	4	of	6
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**Complete if Known**

<i>Application Number</i>	10/695,578
<i>Filing Date</i>	October 27, 2003
<i>First Named Inventor</i>	Scott A. Waldman
<i>Art Unit</i>	To Be Determined
<i>Examiner Name</i>	To Be Determined
<i>Attorney Docket Number</i>	TJU0006-101 (WAL SCO 005)

[illegible][illegible]

**Examiner  
Signature**

Date  
Considered

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 5 of 6

**Complete if Known**

Application Number	10/695,578
Filing Date	October 27, 2003
First Named Inventor	Scott A. Waldman
Art Unit	To Be Determined
Examiner Name	To Be Determined
Attorney Docket Number	TJU0006-101 (WAL_SCO_005)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BD	Banchereau et al., "Immune and clinical responses in patient with metastatic melanoma to CD34 <sup>+</sup> progenitor-derived dendritic cell vaccine," <i>Cancer Research</i> (2001) 61:6451-6458.	
	BE	Bellone et al., "Cancer immunotherapy: synthetic and natural peptides in the balance," <i>Immunology Today</i> (1999) 20(10):457-462.	
	BF	Carrithers et al., "Escherichia coli heat-stable toxin receptors in human colonic tumors," <i>Gastroenterology</i> (1994) 107:1653-1661.	
	BG	Celis et al., "Identification of potential CTL epitopes of tumor-associated antigen MAGE-1 for five common HLA-A alleles," <i>Molecular Immunology</i> (1994) 31(18):1423-1430.	
	BH	Disis et al., "Peptide-based, but not whole protein, vaccines elicit immunity to HER-2/neu, oncogenic self-protein," <i>J. of Immunology</i> (1996) 156:3151-3158.	
	BI	Foon et al., "Clinical and immune responses in resected colon cancer patients treated with anti-idiotypic monoclonal antibody vaccine that mimics the carcinoembryonic antigen," <i>Journal of Clinical Oncology</i> (1999) 17(9):2889-2895.	
	BJ	Herbert et al., <i>The Dictionary of Immunology</i> , Academic Press, 4 <sup>th</sup> ed. (1995).	
	BK	Greenspan et al., "Defining epitopes: It's not as easy as it seems," <i>Nature Biotechnology</i> (1999) 7:936-937.	
	BL	Gura "Systems for identifying new drugs are often faulty," <i>Science</i> (1997) 278:1041-1042.	
	BM	Mallo et al., "Expression of the <i>Cdx1</i> and <i>Cdx2</i> homeotic genes leads to reduced malignancy in colon cancer-derived cells," <i>J. Biological Chemistry</i> (1998) 273(22):14030-14036.	
	BN	Nelson et al., <i>J. Nat'l. Can. Ins.</i> (1996) 88(8):468-488.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 6 of 6

**Complete if Known**

Application Number	10/695,578
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First Named Inventor	Scott A. Waldman
Art Unit	To Be Determined
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Attorney Docket Number	TJU0006-101 (WAL_SCO_005)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BO	Reynolds et al., "Vaccine-induced CD8+ T-cell responses to MAGE-3 correlate with clinical outcome in patients with melanoma," <i>Clinical Cancer Research</i> (2003) 9:657-662.	
	BP	Singh et al., "Isolation and expression of a guanylate cyclase-coupled heat stable enterotoxin receptor cDNA from a human colonic cell line," <i>Biochem. Biophys. Res. Comm.</i> (1991) 179(3):1455-1463.	
	BQ	Smith "Cancer and the immune system," <i>Pediatr Clin North Am.</i> (1994) 41(4) 841-850.	
	BR	Spitler "Cancer vaccines: the interferon analogy," <i>Cancer Biotherapy</i> (1995) 10:1-3.	
	BS	Welzien HU "Renaissance for hapten-specific T lymphocytes: implications for basic and applied research," <i>Z Naturforsch [C]</i> (1992) 47(5-6):323-328.	
	BT	Miller et al., "Improved survival of patients with Melanoma with an antibody response to immunization of a polyvalent melanoma vaccine," <i>Cancer</i> (1995) 75(2):495-502.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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